TITLE: **Review of Advertising**			DOCUMENT NUMBER: **IRB-013**
REVISION NO.: 00	SUPERSEDES/DATE: 00	EFFECTIVE DATE: March 4, 2004	PAGE 1 OF 6

IRB CHAIR OR DESIGNEE:	ACOS R&D:	COMPLIANCE:
Signature	Signature	Signature
Name: Gina Fosheim	Name: Donald Pasquale MD	Name: Yvonne Natale
Date: 2/27/04	Date: 3-1-04	Date: 3/4/04

1 POLICY

It is Stratton VA Medical Center's policy to comply with all applicable local, state, and federal regulations in the conduct of clinical research studies. Written procedures are required for the review of advertising when used to recruit human subjects for participation in research.

2 FORMS

Expedited Review Revision/Amendment Approval letter
Protocol Review Request Form for Revision/Amendment
Full Committee Review Revision/Amendment Approval letter

3 PROCEDURE

3.1 Advertising is considered by the IRB to be part of the informed consent process. Advertising should be included as part of the initial research submission. Advertising not included as part of the initial submission is a revision to the research and must be submitted for review. (Refer to IRB-006 Revisions to Previously Approved Research)

3.1.1 The final copy of the advertisement should be submitted except when a videotape or audiotape will be used.

3.1.2 A written script should be submitted for video or audio advertising before production of the final version to allow for any revisions/changes to the wording that the IRB may require. The final version must be submitted later for review.

3.2 The IRB reviews advertising to assure:

3.2.1 The advertising is not unduly coercive and does not unduly influence subjects by implying benefit, especially those subjects who are likely to be vulnerable.

3.2.2 The advertising does not promise a certainty of benefit beyond that outlined in the research protocol and informed consent.

3.2.3 The advertising makes no implicit or explicit claim that the drug, biologic, device, or research procedure is safe, effective, or is equal or superior to available treatments.

3.2.3.1 Words such as "new treatment", "new medication", or "new drug" are not used without an explanation of the investigational aspects of the research.

3.2.3.2 FDA regulated investigational products must be identified as investigational or experimental.

3.2.4 The advertisement does not emphasize payment or amount of payment.

3.2.5 The advertisement does not promise free medical treatment when the intent is only to say that subjects will not be charged for procedures required by the investigation.

3.3 The IRB recommends that advertisements be limited to the information necessary for potential participants to determine their eligibility and interest. The advertisement may contain the following information:

3.3.1 The name and address of the Principal Investigator and/or the name of the research facility.

3.3.2 The condition under study and/or the purpose of the research.

3.3.3 A summary of criteria used to determine eligibility for the study.

3.3.4 A brief list of the potential benefits of participation, if any.

3.3.5 The approximate time commitment or other commitments of potential participants.

3.3.6 The location of the research and/or whom to contact for further information.

3.4 Any press release related to the research must first be submitted to the Stratton VA Public Relations office for approval. The advertising, with the approval letter from the Public Relations Office, should be submitted to the Research Office for review and approval by the IRB.

3.5 Expedited Review Process:

3.5.1 A member of the IRB staff pre-reviews the advertisement. The IRB Chair or designee conducts the review of the advertisement and may not have a conflict of interest with the research.

3.5.2 The IRB Chair or designee conducting expedited review has the final authority in deciding whether the advertisement qualifies for expedited review and may recommend full committee review.

3.5.3 In order to approve advertisements by expedited review, the reviewer shall determine that criteria for approval of research (38 CFR 16.111) are satisfied.

3.5.4 If the reviewer requests changes or additional information, the IRB staff contacts the Principal Investigator or the designated contact person and requests the information. Upon receipt of the requested information, the changes or additional information is forwarded to the reviewer.

3.5.5 If the reviewer still cannot approve the advertisement as submitted, the Principal Investigator or designated contact person is notified. The Principal Investigator may modify the advertisement for resubmission to the IRB or resubmit the advertisement for review at a full IRB meeting.

3.5.6 If the reviewer recommends full committee review, the Principal Investigator or designated contact person is notified that the advertisement must be reviewed by the full committee and is asked to provide additional copies of the research submission.

3.5.7 The reviewer may not disapprove advertisements under Expedited Review.

3.5.8 If the reviewer finds the advertisement acceptable,

3.5.8.1 The IRB Chair or designee who reviewed the advertisement approves the advertisement.

3.5.8.2 The IRB Chair or designee signs and dates the Expedited Review Revision/Amendment Approval letter.

3.5.8.3 The Expedited Review Revision/Amendment Approval letter is sent to the Principal Investigator. A brief description of the advertisement is included in a parenthetical after the protocol title in the approval letter.

3.5.8.4 The IRB is notified of the approval with a short description of the advertisement in the agenda and in the minutes of the next scheduled IRB meeting.

3.6 Full Committee Review Process:

3.6.1 Advertisements that require full committee review are placed on the agenda of the monthly IRB meeting and are distributed approximately two weeks in advance of the meeting. The advertisement is summarized on the agenda and the agenda identifies all IRB members who are also participating in the research to alert the committee to a conflict of interest.

3.6.2 The IRB staff assigns two primary reviewers, who are not participating in the research, based on their area of expertise.

3.6.3 Committee members are given a copy of the advertisement and the Protocol Review Request Form (Revision/Amendment) to review.

3.6.4 Primary reviewers are given a copy of the advertisement, Protocol Review Request Form (Revision/Amendment), and the primary reviewer sheet to record their comments.

3.6.5 The IRB staff takes minutes at the IRB meeting pertaining to discussion of the advertisement.

3.6.6 Minutes are prepared within one week after the meeting and include:

3.6.6.1 Attendance of IRB members at the meeting.

3.6.6.2 The votes for, against, abstaining, recused, and excused. IRB members with a conflicting interest must recuse themselves from voting.

3.6.6.3 Modifications or any other changes to the advertisement required by the IRB.

3.6.6.4 The basis for requiring changes in or disapproving research.

3.6.6.5 A written summary of any discussion of controverted issues and their resolution.

3.6.7 If the advertisement is approved as submitted,

3.6.7.1 A Full Committee Review Revision/Amendment Approval letter indicating that the advertisement was approved as submitted is sent to the Principal Investigator(s).

3.6.7.2 The Date of Approval for research approved by the full IRB is the date of the IRB meeting at which the advertisement was approved.

3.6.8 If the research is approved with modifications,

3.6.8.1 The modifications must be documented in sufficient detail to allow the IRB staff to verify the changes required by the IRB.

3.6.8.2 A Notification of Approval with Contingencies, listing all required modifications and conditions for approval, is sent to the Principal Investigator(s).

3.6.8.3 The Principal Investigator(s) responds to the Research Office with a copy of all modified documents.

3.6.8.4 The IRB staff reviews the modified documents for confirmation of all modifications required by the IRB.

3.6.8.5 If the submitted documents have not been modified as required, the Principal Investigator(s) is contacted by the IRB staff and asked to submit the complete revision as requested.

3.6.8.6 Once the IRB staff determines that the documents contain all required modifications,

3.6.8.6.1 The IRB Chair or designee reviews the revised documents by Expedited Review and signs the Full Committee Review Revision/Amendment approval letter as per the instructions of the IRB at the full committee meeting at which the revision was reviewed or,

3.6.8.6.2 The modified documents are distributed to all committee members and the original primary reviewers for review and approval at the next full IRB meeting.

3.6.8.7 If the Principal Investigator(s) does not return the required modified documents within 30 days from the date the letter was issued, the IRB staff will notify the IRB Chair or designee to determine a course of action.

3.6.8.8 The Date of Approval is the date of the meeting at which the research was approved with modifications.

3.6.9 If the advertisement is disapproved, the IRB Chair or designee notifies the Principal Investigator in writing of the reasons for the disapproval and offers the Principal Investigator an opportunity to resubmit the revision to the IRB.

3.7 The advertisement and copies of documents received and sent are filed in the Research Office.